

Attorney Docket No.: DEX-0117  
Inventors: Salceda et al.  
Serial No.: 09/721,183  
Filing Date: November 22, 2000  
Page 15

#### REMARKS

Claims 3-7 and 18-37 are pending in the instant application. Claims 3-7 and 18-37 have been rejected. Claims 3-7, 18, 22, 26, 30 and 34 have been amended. Claims 21, 25, 29, 33 and 37 have been canceled. New claims 38 through 42 have been added. Support for these amendments is provided in the claims as originally filed and page 15, lines 6-13 of the specification. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### I. Priority Application

The Examiner has acknowledged U.S. Provisional Application No. 60/166,973, filed November 23, 1999, to describe SEQ ID NO:1, 2, 4 and 5. Accordingly, Applicants have amended independent claims 3 through 7 to be drawn to SEQ ID NO:1 and 2 and added new independent claims 38-42 drawn to SEQ ID NO:18. No new matter is added by this amendment.

#### II. Rejection of Claims 3-7 and 18-37 under 35 U.S.C. 112, second paragraph

Claims 3-7 and 18-37 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner suggests that recitation of

Attorney Docket No.: DEX-0117  
Inventors: Salceda et al.  
Serial No.: 09/721,183  
Filing Date: November 22, 2000  
Page 16

"stringent" conditions does not define the metes and bounds of the physical parameters of the hybridization conditions.

Applicants respectfully disagree.

MPEP 2173 is clear; definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. See MPEP § 2173.02. Stringent is a well known term of art described in detail in teachings such as Sambrook et al. referred to at page 21 of the instant application. Further detailed methodologies for hybridization probes as well as a number of exemplary polynucleotides hybridizing under stringent conditions in accordance with the claimed invention are set forth in the specification at pages 13-14 and page 21 and pages 22, 27, 32, and 37, respectively. Thus, the metes and bounds of this term would be clear to the skilled artisan upon reading the instant specification.

Withdrawal of this rejection under 35 U.S.C. 112, second paragraph is therefore respectfully requested.

III. Rejection of Claims 3-7 and 18-37 under 35 U.S.C. 112, first paragraph - Written Description

Claims 3-7 and 18-37 have been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written

Attorney Docket No.: DEX-0117  
Inventors: Salceda et al.  
Serial No.: 09/721,183  
Filing Date: November 22, 2000  
Page 17

description requirement. In particular, the Examiner suggests that Applicants were not in possession of the genus of polynucleotides that hybridize to the anti-sense of SEQ ID NO:1, 2, 4, 5 or 18.

Applicants respectfully traverse this rejection.

MPEP 2163 states that the written description for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function or structure, or by a combination of such identifying characteristics sufficient to show the applicant was in possession of the claimed genus.

For the genus of polynucleotides hybridizing under stringent conditions to the anti-sense of SEQ ID NO: 1, 2 or 18, the instant specification provides both a representative number of species and structural and functional characteristics. In particular, a number of exemplary species of polynucleotides hybridizing to these sequences are set forth at pages 27 and 32. In addition, SEQ ID NO: 18 is an example of a species hybridizing under stringent conditions to SEQ ID NO:2, and vice versa.

Attorney Docket No.: DEX-0117  
Inventors: Salceda et al.  
Serial No.: 09/721,183  
Filing Date: November 22, 2000  
Page 18

Further, contrary to the Examiner's suggestion the specification provides detailed teachings at pages 13-14 and page 21 concerning hybridization methodologies, thus providing one of skill in the art with information regarding the physical parameters of polynucleotides hybridizing under stringent conditions to SEQ ID NO:1, 2 or 18 as claimed. In addition, the specification references teachings of Sambrook et al. which also provides detailed teachings on the physical parameters of polynucleotides which hybridize under stringent conditions.

Thus, the representative number of species actually reduced to practice and disclosed in the specification, coupled with the disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, meets the written description requirements with respect to stringently hybridizing polynucleotide sequences as claimed.

Withdrawal of this rejection under 35 U.S.C. 112, first paragraph is therefore respectfully requested.

#### IV. Rejection of Claims 3-7 under 35 U.S.C. 102(e)

Claims 3-7 have been rejected under 35 U.S.C. 102(e) as being anticipated by Sun et al. (U.S. 2003/0175715, priority to October 27, 2000). The Examiner suggests that Sun et al. disclose a method for detecting breast cancer, metastasis of breast cancer and a method of staging breast cancer with a

Attorney Docket No.: DEX-0117  
Inventors: Salceda et al.  
Serial No.: 09/721,183  
Filing Date: November 22, 2000  
Page 19

BCG SEQ ID NO:35 which would hybridize to the instant SEQ ID NO:4.

It is respectfully pointed out, however, that the claims have been amended and are no longer inclusive of SEQ ID NO:4, thus mooting this rejection.

Withdrawal of this rejection is therefore respectfully requested.

#### V. Rejection of Claims 4 and 6 under 35 U.S.C. 103(a)

Claims 4 and 6 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Jager et al. (U.S. Patent 6,774,226) in view of Putnam (Metastatic Cancer to the Lung, In: Cancer Principles and Practice of Oncology, De Vita et al. Eds. 1993 Vol. 2, pp. 2678-2679).

The Examiner suggests that it would have been prima facie obvious at the time the claimed invention was made to detect the polynucleotide of SEQ ID NO:15 in the lung, brain or liver as a means of detecting metastatic breast cancer in lung, brain or liver. The Examiner suggests that one of skill in the art would have been motivated to do so by the teachings of Putnam, who identifies these sites for breast metastases and the teachings of Jager et al on the lack of expression of SEQ ID NO:15 in normal brain, liver or lung. The Examiner suggests that SEQ ID NO:15 fulfills the specific embodiment of hybridizing to the instant SEQ ID NO:5 because SEQ ID NO:15 is 93.3% similar to SEQ ID NO:5.

Attorney Docket No.: DEX-0117  
Inventors: Salceda et al.  
Serial No.: 09/721,183  
Filing Date: November 22, 2000  
Page 20

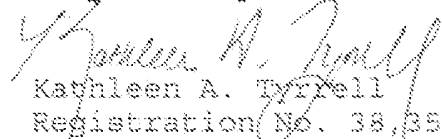
It is respectfully pointed out, however, that the claims have been amended and are no longer inclusive of SEQ ID NO:5, thus mooted this rejection.

Withdrawal of this rejection is therefore respectfully requested.

VI. Conclusion

Applicants believe that this submission overcomes all pending rejections in this case and comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
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